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Attorney Docket No. Q63396
PATENT APPLICATION

#4
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08/29/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Masato HORIE, et al.

Appln. No.: 09/787,360

Group Art Unit: 1653

Confirmation No.: 7873

Examiner: Not Yet Assigned

Filed: March 16, 2001

For: LY6H GENE

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**SUBMISSION OF TRANSLATION OF INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

Commissioner for Patents
Washington, D.C. 20231

Sir:

Attached please find the translation of the International Preliminary Examination Report
form PCT/JP99/05039 for the above-identified application.

Entry of the attached is respectfully requested.

Respectfully submitted,


Gordon Kit

Registration No. 30,764

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67
Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference P99-45	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP99/05039	International filing date (day/month/year) 16 September 1999 (16.09.99)	Priority date (day/month/year) 17 September 1998 (17.09.98)
International Patent Classification (IPC) or national classification and IPC C12N 15/11, 15/63, C07K 14/705, 16/28, A61K 38/17, 48/00, C12Q 1/02, 1/68		
Applicant OTSUKA PHARMACEUTICAL CO., LTD.		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>	
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>	

Date of submission of the demand 07 January 2000 (07.01.00)	Date of completion of this report 02 October 2000 (02.10.2000)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP99/05039

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims. Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP99/05039

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 17-19

because:

☒ the said international application, or the said claims Nos. 17-19 relate to the following subject matter which does not require an international preliminary examination (*specify*):

The subject matters of claims 17-19 relate to a method of therapy for humans which does not require an international preliminary examination by the International Preliminary Examining Authority in accordance with PCT Article 17(2)(a)(i) and Rule 39.1(iv).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 17-19

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP99/05039

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-16	YES
	Claims		NO
Inventive step (IS)	Claims	1-16	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-16	YES
	Claims		NO

2. Citations and explanations

Document 1: Tony, J.F. et al., "Characterization of Two Novel Ly-6 Genes", J. Immunol. (1993), Vol. 150, No. 12, pages 5379-5390

Document 2: Suzan, F. et al., "Analysis of three distinct Ly6-A-related cDNA sequences isolated from rat kidney", Immunogenetics (1990), Vol. 31, No. 2, pages 104-111

Document 3: JP, 3-48696, A (Toray Industries, Inc.), 1 March, 1991 (01.03.91) (Family: none)

Document 4: T. Graubert et al., "Characterization of the murine and human Ly-6 gene clusters", Blood (1997), Vol. 90, No. 1, part 2, page 145B

Document 5: M. Nosten-Bertrand et al., "Normal spatial learning despite regional inhibition of LTP in mice lacking Thy-1", Nature (1996), Vol. 379, pages 826-829

Document 6: Thomas, P. et al., "Tissue expression, structure and function of the murine Ly-6 family of molecules", Immunol. Cell. Biol. (1995), Vol. 73, No. 4, pages 277-296

The subject matters of claims 1-16 appear to be novel since they are not described in any of the documents cited in the ISR. In particular, it is not described in any of the documents that Ly6 family proteins participate in such actions as nerve survival and maintenance, neurotization, glia cell activation and cerebral memory formation.

The subject matters of claims 1-16 appear to involve an inventive step in view of the documents cited in the ISR. The documents do not state that Ly6 family proteins participate in such actions as nerve survival and maintenance, neurotization, glia cell activation and cerebral memory formation. On the other hand, the invention of the present application has advantageous effects in that, due to the above, it can be used in research on the differentiation of neurocytes, for activation of neurocytes, and as a remedy for nervous and mental diseases.